

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



Patents Office  
Government Buildings  
Hebron Road  
Kilkenny

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No. 2001/0255

Date of Filing 16 March 2001

Applicant SALVIAC LIMITED, an Irish company of 39-40 Upper Mount Street, Dublin 2, Ireland.

Dated this 26 day of April 2001.



A handwritten signature in cursive script, likely belonging to the Controller of Patents, Designs and Trademarks.

An officer authorised by the  
Controller of Patents, Designs and Trademarks.

## REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

    X     the grant of a patent under Part II of the Act

           the grant of a short-term patent under Part III of the Act on the basis of the information furnished hereunder.

1. Applicant(s)

Name SALVIAC LIMITED

Address 39-40 Upper Mount Street  
Dublin 2  
Ireland

Description/Nationality

An Irish company

2. Title of Invention

"A system"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date

Country in or for  
which filed

Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed  
by Applicants(s) to be the inventor(s)

Name: Paul Gilson, an Irish citizen.

Address: Uggool, Moycullen, County Galway, Ireland.

Name: Charles Taylor, a British Subject.

Address: Cuckfield Lane, Warninglid, West Sussex RH17 55N, England.

5. Statement of right to be granted a patent (Section 17(2) (b))

The Applicant derives the rights to the Invention by virtue of a Deed of Assignment dated March 15, 2001.

6. Items accompanying this Request – tick as appropriate

- (i)   X   Prescribed filing fee (£100.00)  
(ii)   X   Specification containing a description and claims  
             Specification containing a description only  
        X   Drawings referred to in description or claims  
(iii)        An abstract  
(iv)        Copy of previous application (s) whose priority is claimed  
(v)        Translation of previous application whose priority is claimed  
(vi)   X   Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant (s))

7. Divisional Application (s)

The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....

Filing Date: .....

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name

John A. O'Brien & Associates

Address

The address recorded for the time being in the Register of Patent Agents, and currently Third Floor, Duncairn House, 14 Carysfort Avenue, Blackrock, Co. Dublin, Ireland.

9. Address for Service (if different from that at 8)

As above

Signed



JOHN A. O'BRIEN & ASSOCIATES

Date March 16, 2001



010255

APPLICATION No. \_\_\_\_\_

SALV39/P

- 1 -

"A System"

Introduction

5 This invention relates to a transvascular embolic protection system for safely capturing and retaining embolic material released during an interventional procedure while maintaining blood flow.

10 In our WO-A-99/23976 we have described a vascular filter and a guidewire, the guidewire having a flexible tip at its distal end to assist in navigation of the filter through a potentially tortuous vasculature system. The filter is delivered to a desired location in the vasculature in a delivery catheter. The filter is deployed at the desired location and the delivery catheter is removed over the guidewire. A separate treatment device such as a dilation balloon or a stent of the self-expanding or balloon expandable type is then delivered by a delivery catheter  
15 over the guidewire and deployed at the treatment location. After treatment, the treatment device is withdrawn over the guidewire. The filter is retrieved by introducing a retrieval catheter over the guidewire and pulling the filter back into the retrieval catheter, and with it, any embolic material captured by the filter during the treatment procedure.

20

This system is efficient in effectively capturing embolic material distally while facilitating treatment proximally of the filter.

25 Ideally a range of such devices are provided to suit different procedures and/or patient anatomies.

30 There is however an economic and clinical need to provide a single system of this type that can be used in a wide range of different applications.

Statements of Invention

According to the invention there is provided a method for delivery and deployment of an embolic protection device within a vasculature, the method comprising the steps of:-

advancing a guidewire through a vasculature, the guidewire comprising a distal stop;

advancing a delivery catheter with an embolic protection device loaded into the delivery catheter over the guidewire to a desired location in the vasculature;

advancing a proximal stop over the guidewire;

engaging the proximal stop with the embolic protection device and moving the delivery catheter relative to the proximal stop to deploy the embolic protection device; and

withdrawing the delivery catheter and the proximal stop from the vasculature to leave the bare guidewire in place in the vasculature.

In one embodiment the proximal stop and the delivery catheter are advanced over the guidewire together.

In a preferred embodiment the embolic protection device is deployed by retracting the delivery catheter while maintaining the position of the proximal stop.

In a preferred embodiment the embolic protection device is deployed by advancing the proximal stop while maintaining the position of the delivery catheter.

5 Preferably the loaded delivery catheter is advanced over the guidewire after positioning of the guidewire in the vasculature.

In one embodiment the method comprises the steps of:-

10 on completion of an interventional procedure advancing a retrieval catheter over the guidewire;

engaging the distal stop with the embolic protection device;

15 moving the retrieval catheter distally relative to the distal stop to retrieve the embolic protection device into the retrieval catheter;  
and

20 withdrawing the retrieval catheter and the retrieved embolic protection device from the vasculature.

Preferably the guidewire is retracted to engage the distal stop with the embolic protection device.

25 Ideally the retrieval catheter is advanced to push the deployed embolic protection device into engagement with the distal stop.

30 In one embodiment the embolic protection device is retrieved by advancing the retrieval catheter distally while maintaining the position of the distal stop.

Preferably the embolic protection device is retrieved by retracting the distal stop while maintaining the position of the retrieval catheter.

5 In a preferred embodiment the method comprises the step of advancing a treatment means over the bare guidewire after deployment of the embolic protection device.

10 In a preferred embodiment the method comprises the step of withdrawing the guidewire from the vasculature with the retrieval catheter and the retrieved embolic protection device.

15 In one embodiment the bare guidewire is left in place in the vasculature after withdrawal of the retrieval catheter and the retrieved embolic protection device. Preferably the method comprises the step of advancing a treatment or diagnostic means over the bare guidewire after the withdrawal of the retrieval catheter.

20 In a preferred embodiment the method comprises the step of positioning the guidewire in another location in the vasculature after withdrawal of the retrieval catheter.

25 In one embodiment the method comprises the step of flushing the retrieval catheter before advancing the retrieval catheter over the guidewire.

30 Preferably during advancement of the loaded delivery catheter, at least part of the embolic protection device protrudes distally out of the delivery catheter for atraumatic delivery through the vasculature.



Ideally the protruding part tapers distally inwardly.

In one embodiment the method comprises the step of loading the embolic protection device into the delivery catheter.

5

Preferably the method comprises the step of anchoring the guidewire in the vasculature.

#### Brief Description of the Drawings

10

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

15

Fig. 1 is a schematic side view of an embolic protection device according to the invention;

Fig. 2 is a side view of the embolic protection device of Fig. 1;

20

Fig. 3 is a plan view of the embolic protection device of Fig. 1;

Fig. 4 is a schematic illustration of the embolic protection device of Fig. 1 deployed in a vascular system of a patient;

25

Fig. 5 is a perspective view of a loading assembly according to the invention;

Fig. 6 is a plan view of the assembly of Fig. 5;

Figs. 7 is a side view of a pushing device according to the invention;

Fig. 7(a) is an enlarged side view of a part of the pushing device of Fig. 7;

5 Fig. 8 is a side view of the pushing device of Fig. 7;

Fig. 9 is a side view of the pushing device of Figs. 7 and 8 threaded through the embolic protection device of Fig. 1;

10 Figs. 10 to 12 are side views illustrating loading of the embolic protection device of Fig. 1 into a catheter; and

15 Figs. 13 to 23 are side views illustrating delivery, deployment and retrieval of the embolic protection device of Fig. 1 within the vascular system of Fig. 4.

#### Detailed Description

20 The invention provides a transvascular embolic protection system for safely capturing and retaining embolic material released during an interventional procedure while maintaining blood flow. An assembly is also provided to safely store and prepare the embolic protection system before use.

25 Referring to the drawings and initially to Figs. 1 to 3 thereof there is illustrated an embolic protection device according to the invention, the embolic protection device comprising a collapsible filter element 1 for delivery through a vascular system of a patient and deployment at a desired location in the vascular system.

The filter element 1 comprises a collapsible filter body 2, a collapsible filter support frame 3 contacting the filter body 2, and an inner elongate sleeve 10 to which both the filter body 2 and the frame 3 are mounted.

5 A proximal end 11 of the filter body 2 and a proximal end 12 of the frame 3 are fixedly attached to a proximal end 13 of the sleeve 10, in this case by means of an adhesive bond. A distal end 14 of the filter body 2 and a distal end 15 of the frame 3 are free to slide over a distal end 16 of the sleeve 10.

10 The filter body 2 has a proximal inlet end and a distal outlet end. The inlet end of the filter body 2 has one or more, in this case two, large inlet openings 4 sized to allow blood and embolic material enter the filter body 2, and the outlet end of the filter body 2 has a plurality of, in this case approximately three hundred, small outlet openings 5 sized to allow through passage of blood but to retain  
15 undesired embolic material within the filter body 2.

The filter support frame 3 is movable between a collapsed position for movement of the filter element 1 through a vascular system, and an extended outwardly projecting position to support the filter body 2 in an expanded position, as  
20 illustrated in Figs. 1 to 3. The frame 3 has a distal section 6, an intermediate section 7 for urging the filter body 2 in the expanded position into apposition with a vascular vessel wall, and a proximal section 8 extending proximally and radially inwardly of the intermediate section 7 (Figs. 2 and 3).

25 At least part of the proximal section 8 is spaced distally of the inlet openings 4 in the filter body 2, as illustrated in Figs. 1 and 2, to accommodate inflow of embolic material through the inlets 4 and into the expanded filter body 2. The filter body 2 comprises one or more, in this case two, linking webs 9 between adjacent inlets 4, and a part of the proximal section 8 extends radially inwardly  
30 in alignment with the webs 9, as illustrated in Fig. 3, to avoid occluding the

inlets 4 to the filter body 2 when the filter body 2 is in the expanded position. In this manner the possibility of embolic material becoming caught or hung-up on the proximal section 8 as the embolic material flows distally into the inlet openings 4 is prevented.

5

The proximal section 8 comprises one or more frame elements, in this case four, at least one frame element, in this case two, providing the part of the proximal section 8 which is spaced distally of the inlets 4, and at least one frame element, in this case two, providing the part of the proximal section 8 extending radially inwardly in alignment with the webs 9.

10

The frame elements are of the shape memory material Nitinol, which may have a plating of gold around the Nitinol. The frame elements facilitate movement of the frame 3 between the collapsed position and the extended outwardly projecting position. The frame 3 is electropolished.

15

A guide olive 20 is provided for atraumatic delivery of the filter element 1 through a vascular system, the guide olive 20 being mounted at the distal end 14 of the filter body 2, and tapering distally inwardly. In this case the guide olive 20 is integral with the filter body 2 and is of the material Pellethane. As illustrated in Figs. 1 to 3 the guide olive 20 extends distally of the distal end 16 of the sleeve 10.

20

Fig. 4 illustrates the filter element 1 deployed in a vasculature 21 downstream of a stenosed region 22 in the vascular system. The region of the vasculature 21 in which the filter element 1 is deployed must be substantially straight for a length at least equal to the longitudinal length of the filter element 1 to ensure apposition of the filter body 2 with the vasculature wall. By directly mounting the guide olive at the distal end 14 of the filter body 2 the longitudinal length of the filter element 1 is reduced to define a longitudinally compact filter element 1.

25

30

Thus, the user has greater freedom when choosing a site in the vasculature 21 to deploy the filter element 1 because the length of the vasculature 21 which is required to be straight is correspondingly reduced.

5

Referring to Figs. 5 to 12 there is illustrated an assembly 30 for loading the collapsible filter element 1 into a catheter.

10

The assembly 30 comprises a delivery catheter 31 defining a reception space 34 at a distal end 32 of the delivery catheter 31 for receiving the collapsed filter element 1. There is a separate loading device 33 to collapse the filter element 1, and a separate removable pushing device 35 for delivering the filter element 1 through the loading device 33 and into the reception space 34. An internal proximal stop is in this case provided by an inner catheter 38 for engagement with the collapsed filter element 1 to disassociate the loaded delivery catheter 31 from the loading device 33. The assembly also comprises and a tray 50.

15

20

The loading device 33 defines an inlet end 36 and an outlet end 37, the inlet end 36 defining a larger cross-sectional area than the outlet end 37, and the outlet end 37 being configured for co-operative alignment with the reception space 34, as illustrated in Figs. 10 and 11.

25

The loading device 33 has means for radially compressing the filter element 1 from the extended outwardly projecting position of Fig. 10 to the collapsed position of Fig. 11. In this case the loading device 33 comprises a main support having a funnel-shaped bore formed from a frusto-conical filter element receiving portion terminating in a cylindrical portion formed by a thin-walled loading tube projecting from the main support for positioning within the reception space 34. The cone angle of the bore is chosen from an angle in the range of between 15°

and 65°, preferably between 35° and 45°. The loading tube is formed from polytetrafluoroethylene or PET, and is mounted on a metal spigot attached to the main support which is formed from "perspex" or a similar material. The loading tube may be coated with a lubricant.

5

The pushing device 35 comprises a handle 39 for gripping the loading device 35, and an elongate stem, in this case provided by a wire 40, extending from the handle 39 for threading through the filter element 1. The wire 40 defines a distal stop 41 for releasably engaging with the filter element 1 to push the filter element 1 through the loading device 33, thereby collapsing the filter element 1, and into the reception space 34.

10

15

As illustrated in Fig. 7, the distal stop 41 is integral with the wire 40, and the distal stop 41 is provided by a step in the wire 40 from a small diameter portion proximal of the step to a large diameter portion distal of the step. The small diameter is approximately 0.014" (0.3556 mm) and the large diameter is approximately 0.018" (0.4572 mm).

20

In this case the large diameter portion of the wire 40 extends distally to the handle 39 (Fig. 7). However it will be appreciated that the large diameter portion may be only a locally defined feature on the wire 40.

25

It will also be appreciated that the distal stop 41 may be attached to the wire 40, for example by adhesive means or by mechanical keying means or by brazing, or soldering, or welding, or by any other suitable means of attachment of the distal stop 41 to the wire 40.

The wire 40 has a low friction coating, for example of polytetrafluoroethylene, for ease of threading of the wire 40 through the filter element 1.

The handle 39 facilitates ease of gripping and use of the pushing device 35.

5 The delivery catheter 31 and the inner catheter 38 facilitate the transvascular delivery of the filter element 1 to a desired location in the vascular system and the deployment of the filter element 1 at the desired location. In the delivery configuration illustrated in Figs. 10 to 12, the distal end 32 of the delivery catheter 31 extends distally of a distal end 59 of the inner catheter 38 to define the reception space 34. The inner catheter 38 is restrained from moving any  
10 further proximally relative to the delivery catheter 31, however the inner catheter 38 may be moved distally relative to the delivery catheter 31 from the delivery configuration, illustrated in Figs. 10 to 12, to facilitate deployment of the filter element 1.

15 The delivery catheter 31 has a flushing port 55 at a proximal end 56 of the delivery catheter 31, and the inner catheter 38 has a flushing port 57 at a proximal end 58 of the inner catheter 38.

20 The delivery catheter 31 and the inner catheter 38 at least partially comprise a stiff core, for example of a metallic material, such as stainless steel, encased in a more pliable body, for example of a plastics material, such as polyamide. The cores comprise a mesh of longitudinally oriented strips of the stiff material and circumferentially oriented strips of the stiff material.

25 The tray 50 comprises a first retaining means for releasably supporting the loading device 33 in co-operative alignment with the catheter 31 before loading and during the loading procedure, as illustrated in Figs. 5 to 11, and a second retaining means for releasably supporting the pushing device 35 in the disengaged position illustrated in Figs. 5 and 6 before delivering the filter  
30 element 1 through the loading device 33 and into the reception space 34. In this

case the first retaining means comprises a channel 51 extending around the tray 50 for receiving the catheter 31 in a looped configuration (Fig. 6) and the loading device 33, and a plurality of projections spaced along the channel wall projecting inwardly for snap retention of the loading device 33 and the catheter 31 in position, as illustrated in Fig. 6. The second retaining means comprises the channel 51 and a plurality for retaining projections on the channel wall for snap retention of the handle 39 in the position illustrated in Figs. 5 and 6, so that the distal stop 41 does not engage the filter element 1 before the loading procedure.

10 A liquid retaining bath 52 is provided by recesses in the tray 50, the bath 52 having a depth sufficient to accommodate in a totally submerged state the reception space 34 of the catheter 31 and the filter element 1 for submerged loading of the filter element 1 through the loading device 33 into the reception space 34. As illustrated in Fig. 6, the channel 51 communicates with the bath 15 52, and a ramp is provided at an end of the channel 51 communicating with the bath 52 to direct the reception space 34 downwards towards the bottom of the bath 52 but supporting the distal end 32 of the delivery catheter 31 above the bottom of the bath 52 by means of a step.

20 A syringe 53 is provided for flushing the catheter 31, the inner catheter 38, the loading device 33 and the filter element 1. A recess 54 is provided in the tray 50 for snap retention of the syringe 53 before use.

25 The assembly 30 is assembled before use by positioning the loading device 33 in the channel 51 of the tray 50, as illustrated in Figs. 5 and 6, and snapping the loading device 33 into place so that it is releasably supported by the first retaining means. The catheter 31 is then looped through the channel 51 and snapped into place by the first retaining means so that the thin-walled loading tube of the loading device 33 projects into the reception space 34, as illustrated in 30 Fig. 10.



The wire 40 of the pushing device 35 is threaded through the filter element 1, the proximal end of the wire 40 is inserted through the loading device 33 and extended partially through the inner catheter 38. The handle 39 is snapped into place in the channel 51, as illustrated in Figs. 5 and 6, by the second retaining means. In this configuration the filter element 1 is slidable over the wire 40 but is normally positioned within the bath 52 (Fig. 6). The syringe is also snapped into place in recess 54.

10 The assembly is now ready to be sealed and stored until required.

In this storage configuration the filter element 1 is in the extended outwardly projecting position. This is advantageous. If the filter element 1 were loaded into the catheter 31 and stored in the collapsed position for a long period of time, the filter element 1 would be subject to material deformation, in particular to material creep.

The assembly may be safely stored for long periods in a packaged configuration without risk of filter element material deformation.

20 When the assembly 30 is required for use, the seal around the assembly 30 is broken and the syringe 53 is removed from the recess 54. The flushing port 55 is rotated through 90° to release the flushing port 55 from a snap-fit retaining means in the tray 40 in a "bolt-action". The syringe 53 is then used to flush the inner catheter 38 and the delivery catheter 31 with, for example, a saline solution through the flushing ports 57, 55 respectively, and also to immerse the filter element 1 and the reception space 34 of the delivery catheter 31 with the saline solution by filling the bath 52 with the saline solution. This ensures that all air bubbles and other unwanted material are removed from the system.

30

This flushing step is performed shortly before intended use. The filter element 1 is completely visible to the user during prepping. In this way the user can squeeze or pinch parts of the filter element 1 to ensure the filter element 1 is completely flushed of air. This would not be possible if the filter element 1 was loaded into the catheter 31 upon assembly and stored for a potentially long period in the collapsed position.

The flushed filter element 1 is now ready for loading. The pushing device 35 is released from the second retaining means by a "bolt-action" rotation of the handle 39 through 90° around an axis defined by the wire 40. The released pushing device 35 is then free to slide proximally through the filter element 1, the loading device 33 and the inner catheter 38 until the distal stop 41 engages the filter element 1 (Fig. 9). Continued pushing of the pushing device 35 will push the filter element 1 proximally towards the loading device 33 (Fig. 10), through the loading device 33, thereby collapsing the filter element 1 from the extended outwardly projecting position of Fig. 10 to the collapsed position of Fig. 11, and into the reception space 34 until the filter element 1 abuts the inner catheter 38 (Fig. 11).

The loading device 33 has remained in co-operative alignment with the catheter 31 by means of the first retaining means up to this stage in the procedure. Because the flushing port 55 has been released from the snap-fit retaining means in the tray 50, the loaded catheter 31 and the inner catheter 38 are free to slide proximally in the channel 51 away from the loading device 33. Pushing of the pushing device 35 towards the proximal end of the delivery catheter 31 pushes the inner catheter 38 towards the proximal end of the delivery catheter 31, and because further proximal movement of the inner catheter 38 relative to the delivery catheter 31 is not possible the delivery catheter 38 is also pushed towards the proximal end of the delivery catheter 31. In this manner the delivery

catheter 31, the inner catheter 38 and the collapsed filter element 1 are all moved together towards the proximal end of the delivery catheter 31 relative to the loading device 33, thereby disassociating the loaded catheter 31 from the loading device 33.

5

The loaded catheter 31 and the inner catheter 38 can now be removed from the channel 51 leaving the loading device 33 and pushing device 35 behind in the channel 51. The loaded catheter 31 and the inner catheter 38 are now ready for insertion into a vascular system of a patient.

10

The loading assembly according to the invention provides a simple and convenient means of loading a filter element into a catheter.

15

The filter element is loaded by a simple, single-direction pushing action. This minimises potential loading difficulties.

The elements of the assembly are retained in the correct loading alignments by the tray.

20

The pushing device is completely separated from the loaded catheter after completion of the loading procedure. This means that the pushing device may be reused for loading of other filter elements, if desired.

25

In addition, the loaded filter element is not attached or associated in any way with the pushing device. Thus, the user is free to choose any suitable guidewire, as desired, for subsequent delivery of the filter element through a vascular system of a patient.

30

Referring to Fig. 4 and Figs. 13 to 23 there is illustrated a medical guidewire 70 according to the invention for exchange of medical devices, such as the filter

element 1, through the vasculature 21 over the guidewire 70. The guidewire 70 defines a distal end 71 and comprises a distal stop 72 to prevent relative movement of the filter element 1 distally of the distal end 71. The portion of the guidewire 70 proximally of the distal stop 72 is bare for exchange of the filter element 1 and/or other medical devices over the guidewire 70 while the guidewire 70 remains in the vasculature 21.

In this case the distal stop 72 is integral with the guidewire 70 and comprises a step in the guidewire 70 from a small diameter portion proximal of the step to a large diameter portion distal of the step. The small diameter is approximately 0.014" (0.3556 mm) and the large diameter is approximately 0.018" (0.4572 mm). A curve may be formed towards the distal end 71 of the guidewire 70 to facilitate greater freedom when positioning the guidewire 70.

With reference to Fig. 13, it may be seen that the large diameter portion of the guidewire 70 extends distally of the step to the distal end 71 of the guidewire 70. However, it will also be appreciated that the large diameter portion of the guidewire 70 may extend distally of the step only a part of the distance to the distal end 71 of the guidewire 70. The large diameter portion may taper inwardly distally of the step back to the small diameter in an arrow-head type shape. The distal stop 72 may be attached to the guidewire 70, for example by an adhesive, or by a mechanical keying means, or by brazing, or soldering, or welding, or by any other suitable means of attachment of the distal stop 72 to the guidewire 70. It will be appreciated that a variety of configurations are possible for the distal stop 72 to achieve its function of preventing relative movement of the filter element 1 distally of the distal end 71 of the guidewire 70.

The guidewire 70 is partially of stainless steel and partially of a radiopaque material to aid the user in positioning the guidewire 70 accurately in the vasculature 21. The guidewire 70 has a coating of a low friction material, for

example of a fluoropolymer such as polytetrafluoroethylene, or of a silicone material, or of a hydrophilic material, for ease of advancement of the guidewire 70 through the vasculature 21 and ease of exchange of the filter element 1 and/or other medical devices over the guidewire 70.

5

Referring to Fig. 4 and Figs. 13 to 23 there is illustrated an embolic protection system according to the invention for the delivery, deployment and retrieval of the filter element 1 within the vasculature 21.

10

The embolic protection system comprises the guidewire 70 with the distal stop 72 for advancing through the vasculature 21, the filter element 1, the delivery catheter 31 for delivering the collapsed filter element 1 over the guidewire 70 to a desired location in the vasculature 21, the proximal stop, being provided by the inner catheter 38, for deployment of the filter element 1, and a retrieval catheter 80 advanceable over the guidewire 70 for retrieval and withdrawal of the filter element 1.

15

20

To deliver the filter element 1 to a desired location in the vasculature 21, the guidewire 70 is first inserted into the vascular system of a patient on its own and advanced through the vasculature 21 (Fig. 13) until the distal stop 72 is distal of the region of stenosis 22.

25

The guidewire 70 may be anchored in a bend in the vasculature 21 distally of the region of stenosis 22, as illustrated in Fig. 4, to facilitate some straightening of the anatomy by the user prior to delivery of the filter element 1.

30

The loaded delivery catheter 31 and the inner catheter 38 are then inserted into the vascular system and advanced over the guidewire 70 through the vasculature 21 (Fig. 14) until the collapsed filter element 1 is at a desired location in the vasculature distally of the stenosed region 22 (Fig. 15). At least part of the

collapsed filter element 1, in this case part of the guide olive 20, protrudes distally out of the delivery catheter 31 for atraumatic delivery of the loaded delivery catheter 31 through the vasculature 21.

5 The delivery catheter 31 is retracted while maintaining the position of the inner catheter 38 (Fig. 16). During retraction of the delivery catheter 31 the filter element 1 is freely slidable over the guidewire 70. By maintaining the position of the inner catheter 38 during retraction of the outer catheter 31, the inner catheter 38 acts as a proximal stop against which the filter element 1 abuts. In this way  
10 the inner catheter 38 facilitates deployment of the filter element 1 from the collapsed position of Fig. 15 to the extended outwardly projecting position of Fig. 17.

15 Alternatively, the filter element 1 is deployed by advancing the inner catheter 38 while maintaining the position of the delivery catheter 31. In this case the inner catheter 38 acts as a pusher to facilitate deployment of the filter element 1.

It will be appreciated that the filter element 1 may be deployed by any sufficient movement of the delivery catheter 31 proximally relative to the inner catheter 38  
20 thereby engaging the inner catheter 38 with the filter element 1 to facilitate deployment of the filter element 1.

The stiff cores in the delivery catheter 31 and the inner catheter 38 prevent deformation of the delivery catheter 31 and the inner catheter 38 during  
25 deployment of the filter element 1. In particular, the orientation of the cores prevent elongation of the delivery catheter 31 and prevent compression of the inner catheter 38 as the delivery catheter 31 is moved proximally relative to the inner catheter 38 to facilitate deployment of the filter element 1. This ensures that the filter element 1 is accurately and smoothly deployed in the desired  
30 location in the vasculature 21.

In the extended outwardly projecting position the filter body 2 is in complete circumferential apposition with the wall of the vasculature 21 over a length substantially equal to the intermediate section 7 of the filter support frame 3.

5

After deployment of the filter element 1 both the delivery catheter 31 and the inner catheter 38 are retracted and withdrawn from the vasculature 21 (Figs. 17 and 18) leaving the guidewire 70 in place in the vasculature 21, and the deployed filter element 1 in place in the vasculature 21 distally of the stenosed region 22.

10

The guidewire 70 is not attached to the filter element 1 and thus it is free to rotate and/or move longitudinally relative to the filter element 1. This is highly advantageous as it prevents any accidental movement of the guidewire 70 causing a twisting of and/or dislodging of the deployed filter element 1. Thus, the user has more freedom to carry out a treatment procedure on the stenosed region 22 without the risk of intimal abrasion, or of the deployed filter element 1 becoming dislodged or in some other way creating a potential flow path for embolic material around the filter element 1.

15

20

In addition, the portion of the guidewire 70 in place in the vasculature 21 proximal of the distal stop 72 is bare. This facilitates the exchange of a wide variety of medical devices, for example a treatment means, over the bare guidewire 70 while the deployed filter element 1 remains in position in the vasculature 21. Examples of such medical devices are atherectomy devices to carry out an atherectomy procedure on the stenosed region 22, or an angioplasty balloon to carry out an angioplasty procedure on the stenosed region 22, or a stent to carry out a stenting procedure on the stenosed region 22, or any possible combination of these procedures, or any other therapeutic procedure known to dislodge material.

25

30

After completion of an interventional procedure, for example a treatment of the stenosed region 22, the retrieval catheter 80 is flushed with, for example a saline solution, using the syringe 53 and the retrieval catheter 80 is inserted into the vascular system and advanced over the bare guidewire 70 until a distal end 81 of the retrieval catheter 80 is immediately proximal of the deployed filter element 1 (Fig. 19).

The guidewire 70 is retracted to engage the distal stop 72 with the filter element 1 (Fig. 20). The distal stop 72 may engage with any suitable engagement point on the filter element 1. Referring to Fig. 20 and Fig. 2, the distal stop 72 is retracted partially within the guide olive 20, the distal stop 72 engaging, in this case, the distal end 16 of the sleeve 10.

The illustrations of the filter element 1 in Figs. 13 to 23 do not show all of the detail of Figs. 1 to 3, for example the inner sleeve 10 is not shown in Fig. 20, to avoid unduly cluttering the more schematic illustrations in Figs. 13 to 23. However, it will be appreciated that the filter element 1 comprises the features as described previously with particular reference to Figs. 1 to 3.

Alternatively, the guidewire 70 is not retracted and the retrieval catheter 80 is advanced further distally to engage the deployed filter element 1 and push the deployed filter element 1 distally until the distal end 16 of the sleeve 10 engages the distal stop 72.

Alternatively, a combination of retraction of the guidewire 70 and advancement of the retrieval catheter 80 may be employed to cause engagement of the distal stop 72 with the distal end 16 of the sleeve 10.

The retrieval catheter 80 is then advanced distally while maintaining the position of the distal stop 72 of the guidewire 70, thereby collapsing the filter element 1



(Fig. 21) from the extended outwardly projecting position to the collapsed position, until the filter element 1 is fully collapsed and retrieved within the distal end 81 of the retrieval catheter 80.

5      Alternatively, the distal stop 72 of the guidewire 70 is retracted while maintaining the position of the retrieval catheter 80 to collapse and retrieve the filter element 1 into the distal end 81 of the retrieval catheter 80.

10      Alternatively, a combination of advancement of the retrieval catheter 80 and retraction of the guidewire 70 may be employed to cause collapse and retrieval of the filter element 1 into the distal end 81 of the retrieval catheter 80.

15      The distal stop 72 facilitates retrieval of the filter element 1 by preventing the filter element 1 moving distally off the distal end 71 of the guidewire 70.

20      The guide olive 20 may or may not protrude distally out of the distal end 81 of the retrieval catheter 80 after collapse of the filter element 1.

25      The retrieval catheter 80 and the retrieved filter element 1 are then withdrawn from the vasculature 21 (Fig. 22).

30      The guidewire 70 may be withdrawn from the vasculature 21 with the retrieval catheter 80 and the retrieved filter element 1, or alternatively the bare guidewire 70 may be left in place in the vasculature 21 after withdrawal of the retrieval catheter 80 and the retrieved filter element 1 (Fig. 23). When the bare guidewire 70 is left in place in the vasculature 21, a further treatment or diagnostic means may be advanced over the bare guidewire 70 to access any desired location in the vasculature 21. The position of the bare guidewire 70 may be adjusted either proximally or distally, as desired, after withdrawal of the retrieval catheter 80 and the retrieved filter element 1. Typically a diagnostic means is advanced at

this stage to facilitate angiographic assessment of the treatment site with the bare guidewire 70 in place in the vasculature 21.

5 The embolic protection device is not restricted to use with a particular guidewire because it is not attached or engaged with the guidewire in any way as it is advanced over the guidewire. This is highly advantageous. If the guidewire proves unsuitable for some reason, for example because it is too large or not trackable enough to access the desired site in the vascular system, the guidewire may be replaced with a more suitable guidewire. However, because the embolic  
10 protection device is independent of the guidewire it may be used with any suitable guidewire, incorporating a stop.

The invention gives greater freedom to a user by providing a choice of guidewires to suit a patient anatomy without requiring the user to select the  
15 embolic protection device to be used with the guidewire until after successful crossing of the lesion with the guidewire.

The invention is not limited to the embodiments hereinbefore described with reference to the accompanying drawings, which may be varied in construction  
20 and detail.

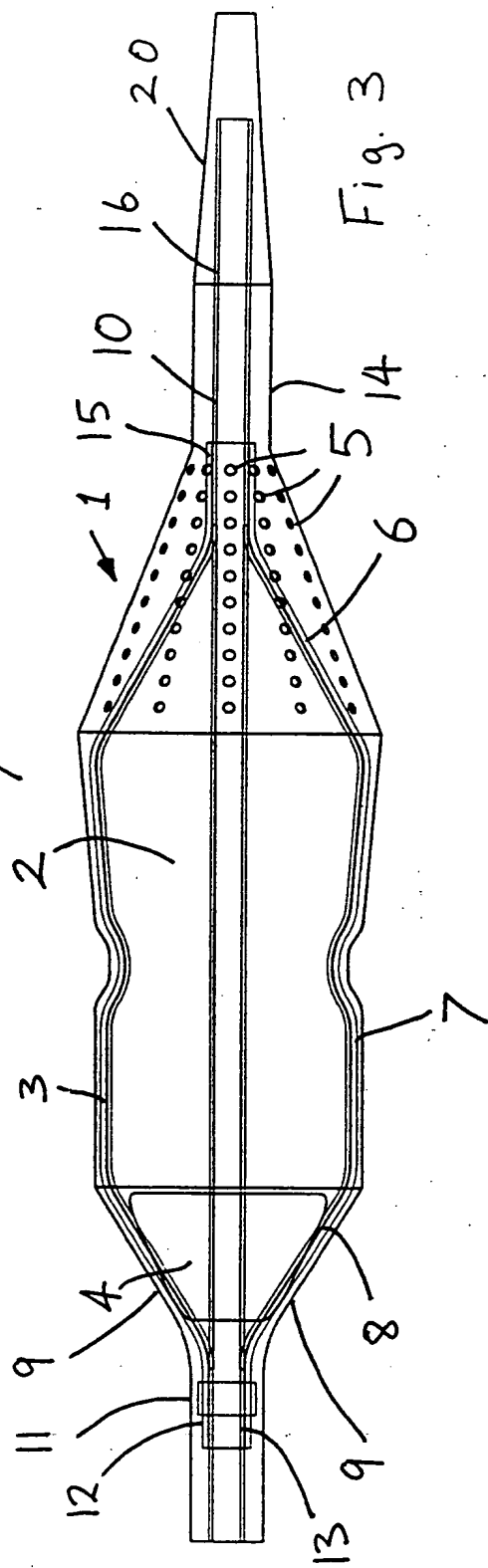
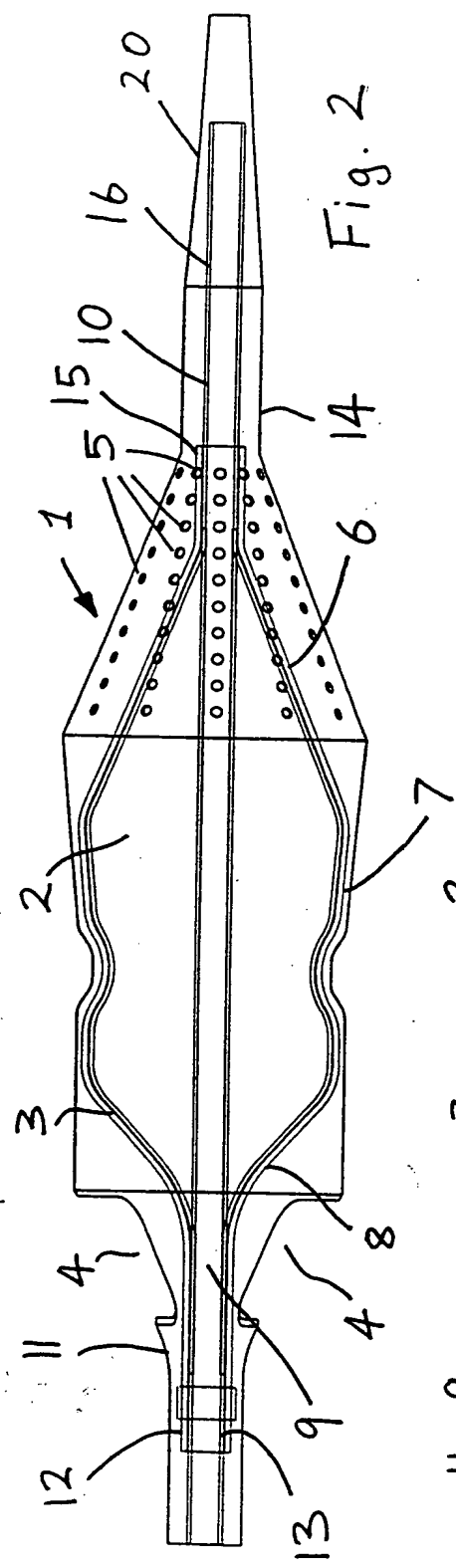
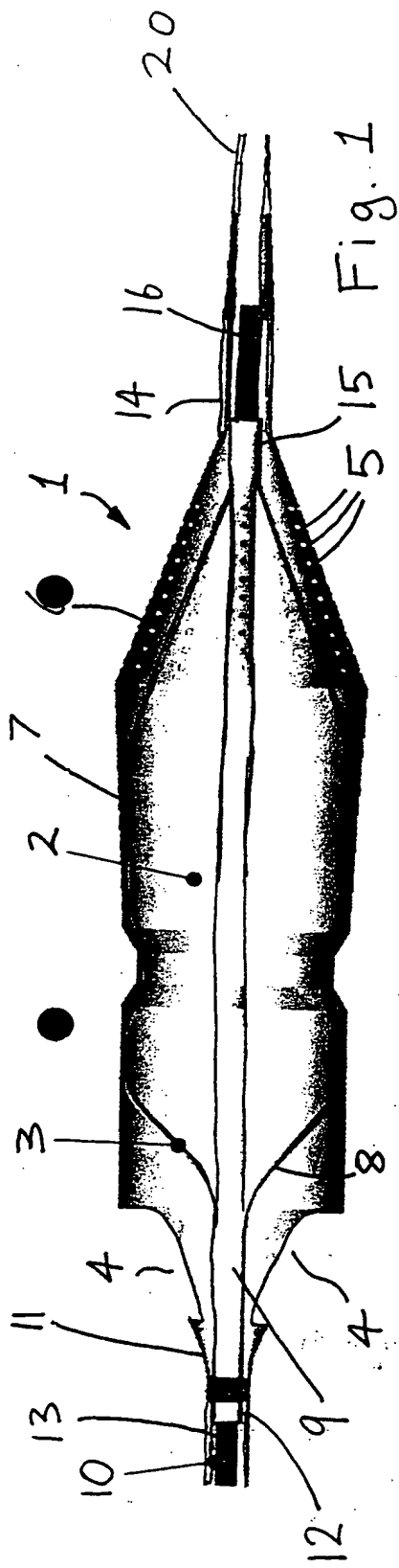
Claims

1. A method for delivery and deployment of an embolic protection device within a vasculature, the method comprising the steps of:-
- 5
- advancing a guidewire through a vasculature, the guidewire comprising a distal stop;
- 10
- advancing a delivery catheter with an embolic protection device loaded into the delivery catheter over the guidewire to a desired location in the vasculature;
- advancing a proximal stop over the guidewire;
- 15
- engaging the proximal stop with the embolic protection device and moving the delivery catheter relative to the proximal stop to deploy the embolic protection device; and
- 20
- withdrawing the delivery catheter and the proximal stop from the vasculature to leave the bare guidewire in place in the vasculature.
2. A method as claimed in claim 1 wherein the proximal stop and the delivery catheter are advanced over the guidewire together.
- 25
3. A method as claimed in claim 1 or 2 wherein the embolic protection device is deployed by retracting the delivery catheter while maintaining the position of the proximal stop.

4. A method as claimed in claim 1 or 2 wherein the embolic protection device is deployed by advancing the proximal stop while maintaining the position of the delivery catheter.
5. A method as claimed in any of claims 1 to 4 wherein the loaded delivery catheter is advanced over the guidewire after positioning of the guidewire in the vasculature.
6. A method as claimed in any of claims 1 to 5 wherein the method comprises the steps of:-
- on completion of an interventional procedure advancing a retrieval catheter over the guidewire;
- engaging the distal stop with the embolic protection device;
- moving the retrieval catheter distally relative to the distal stop to retrieve the embolic protection device into the retrieval catheter;
- and
- withdrawing the retrieval catheter and the retrieved embolic protection device from the vasculature.
7. A method as claimed in claim 6 wherein the guidewire is retracted to engage the distal stop with the embolic protection device.
8. A method as claimed in claim 6 wherein the retrieval catheter is advanced to push the deployed embolic protection device into engagement with the distal stop.

9. A method as claimed in any of claims 6 to 8 wherein the embolic protection device is retrieved by advancing the retrieval catheter distally while maintaining the position of the distal stop.
- 5 10. A method as claimed in any of claims 6 to 8 wherein the embolic protection device is retrieved by retracting the distal stop while maintaining the position of the retrieval catheter.
- 10 11. A method as claimed in any of claims 1 to 10 wherein the method comprises the step of advancing a treatment means over the bare guidewire after deployment of the embolic protection device.
- 15 12. A method as claimed in any of claims 6 to 11 wherein the method comprises the step of withdrawing the guidewire from the vasculature with the retrieval catheter and the retrieved embolic protection device.
- 20 13. A method as claimed in any of claims 6 to 11 wherein the bare guidewire is left in place in the vasculature after withdrawal of the retrieval catheter and the retrieved embolic protection device.
- 25 14. A method as claimed in claim 13 wherein the method comprises the step of advancing a treatment or diagnostic means over the bare guidewire after the withdrawal of the retrieval catheter.
15. A method as claimed in claim 13 or 14 wherein the method comprises the step of positioning the guidewire in another location in the vasculature after withdrawal of the retrieval catheter.

16. A method as claimed in any of claims 6 to 15 comprising the step of flushing the retrieval catheter before advancing the retrieval catheter over the guidewire.
- 5 17. A method as claimed in any of claims 1 to 16 wherein during advancement of the loaded delivery catheter, at least part of the embolic protection device protrudes distally out of the delivery catheter for atraumatic delivery through the vasculature.
- 10 18. A method as claimed in claim 17 wherein the protruding part tapers distally inwardly.
- 15 19. A method as claimed in any of claims 1 to 18 wherein the method comprises the step of loading the embolic protection device into the delivery catheter.
20. A method as claimed in any of claims 1 to 19 wherein the method comprises the step of anchoring the guidewire in the vasculature.
- 20 21. A method for delivery and deployment of an embolic protection within a vasculature substantially as hereinbefore described with reference to the accompanying drawings.



2/10

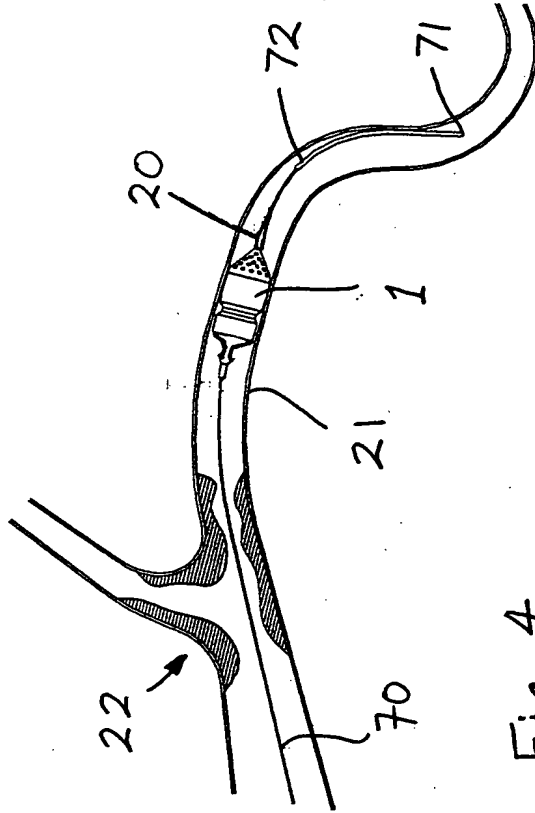
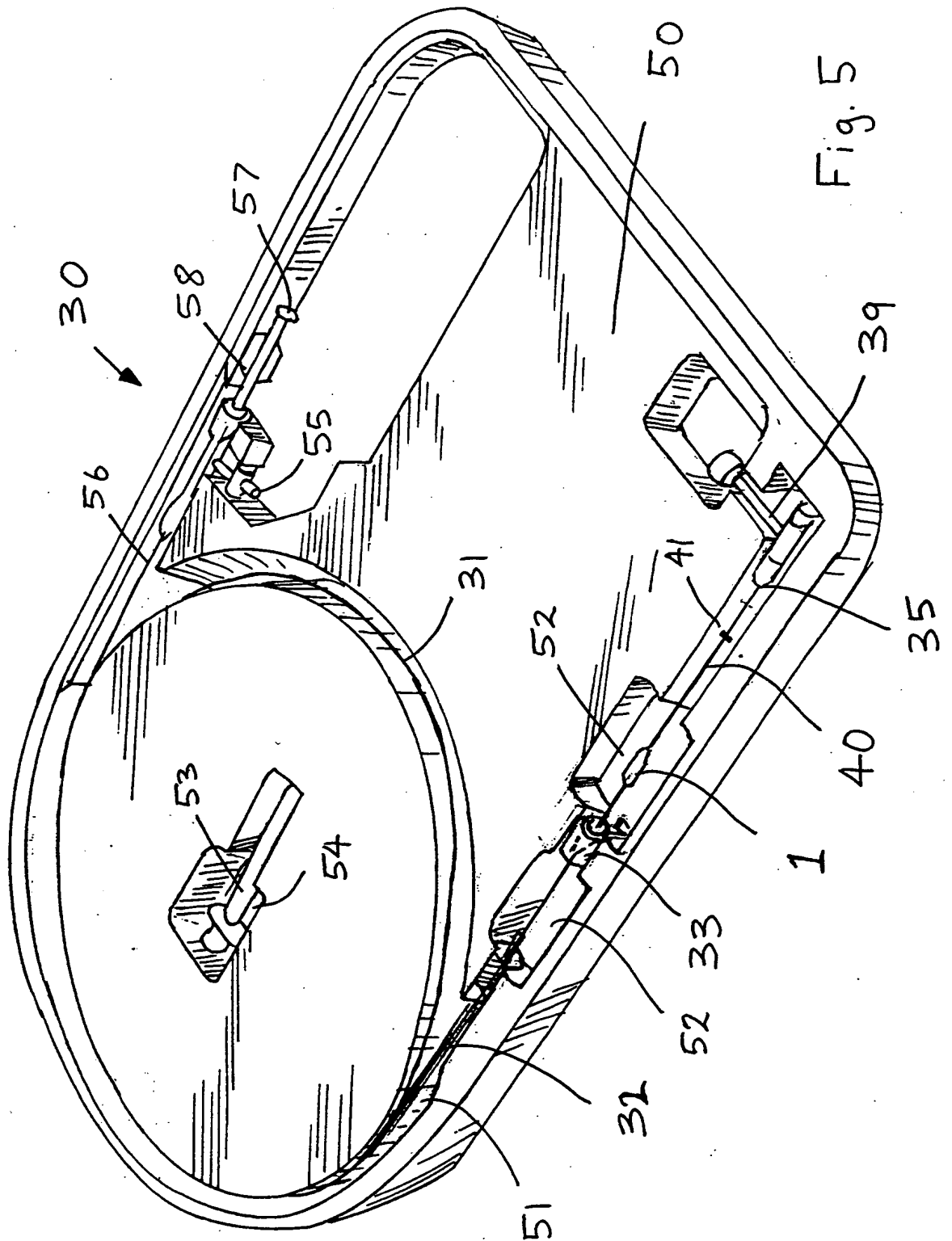


Fig. 4

87 P U





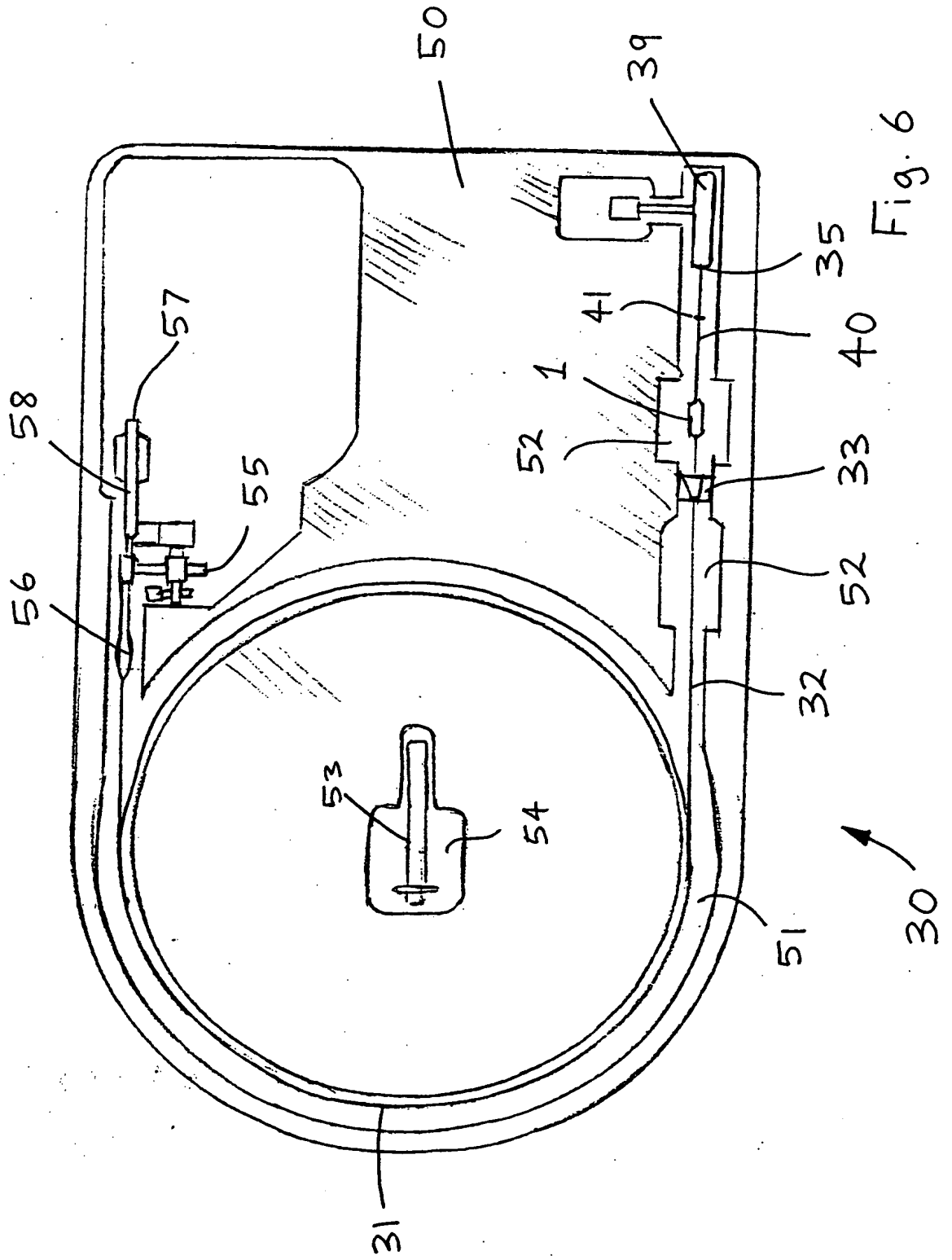


Fig. 6

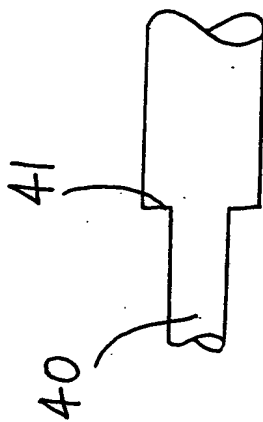


Fig. 7(a)

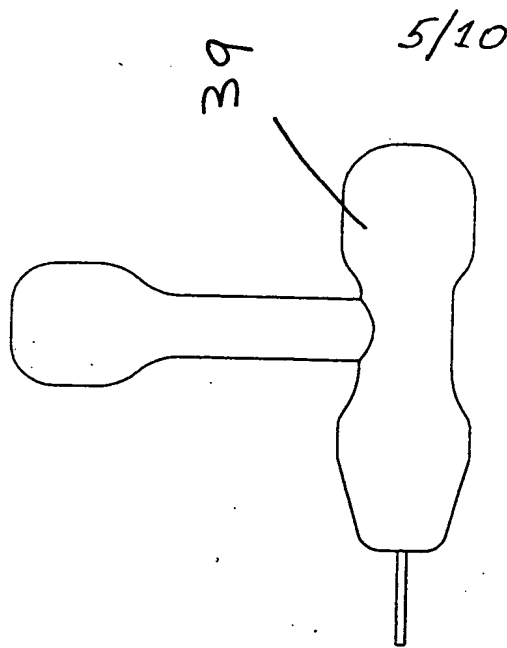
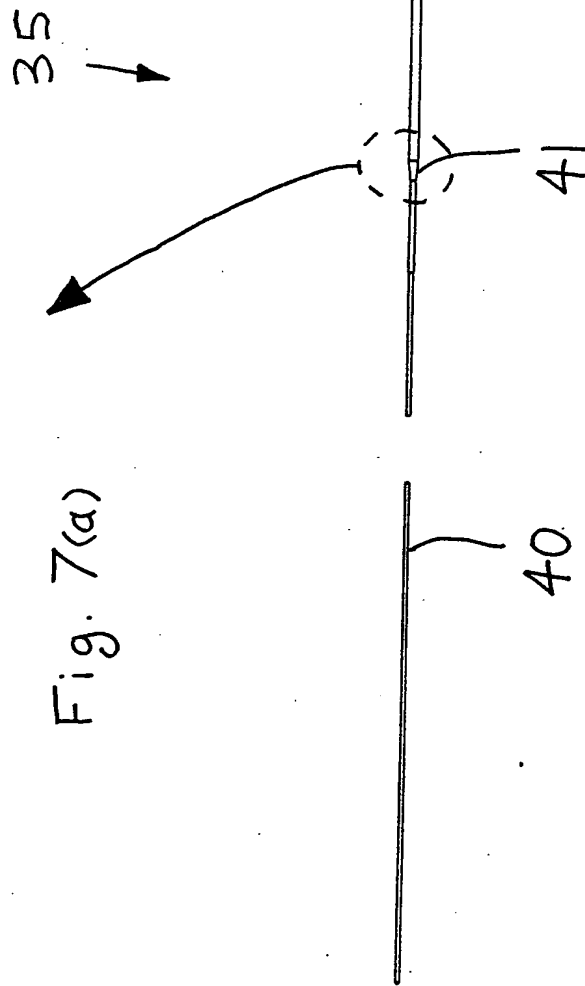


Fig. 7



Fig. 8

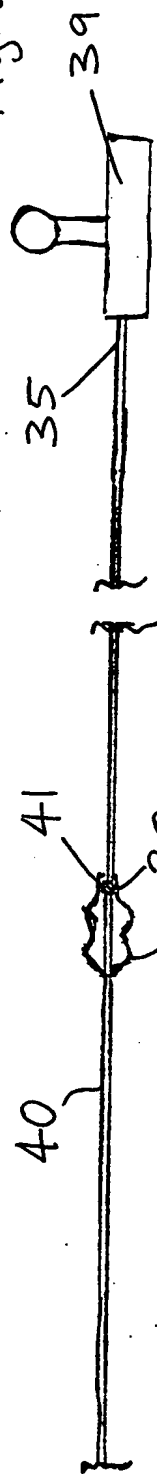


Fig. 9

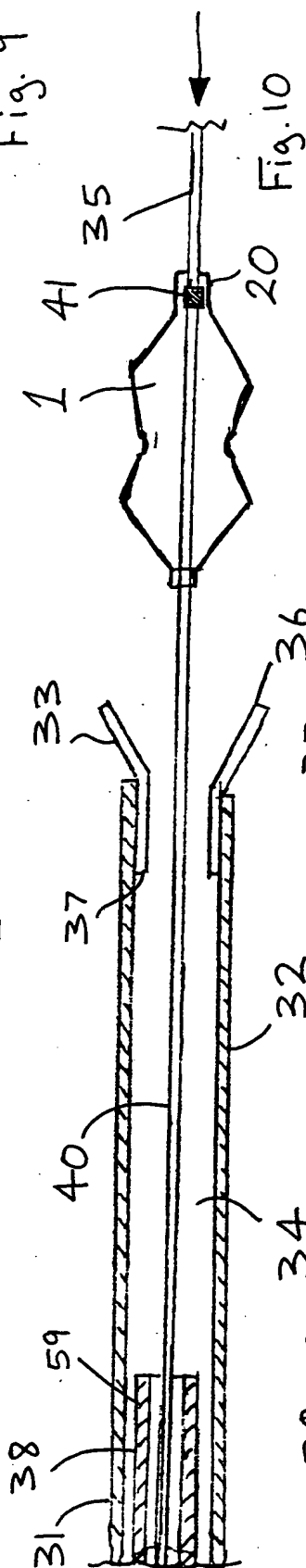


Fig. 10

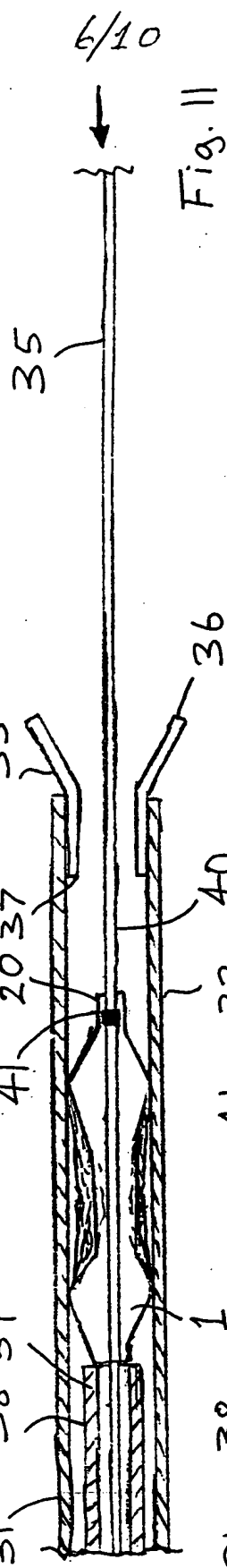


Fig. 11

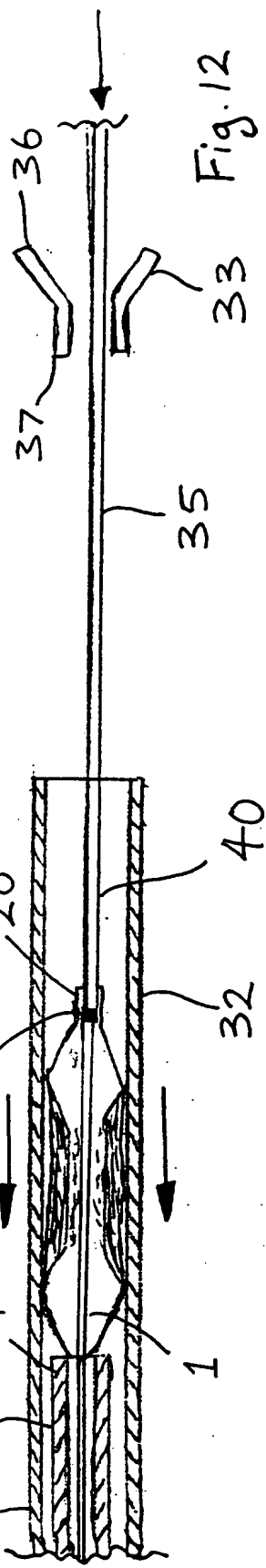


Fig. 12

Fig. 13

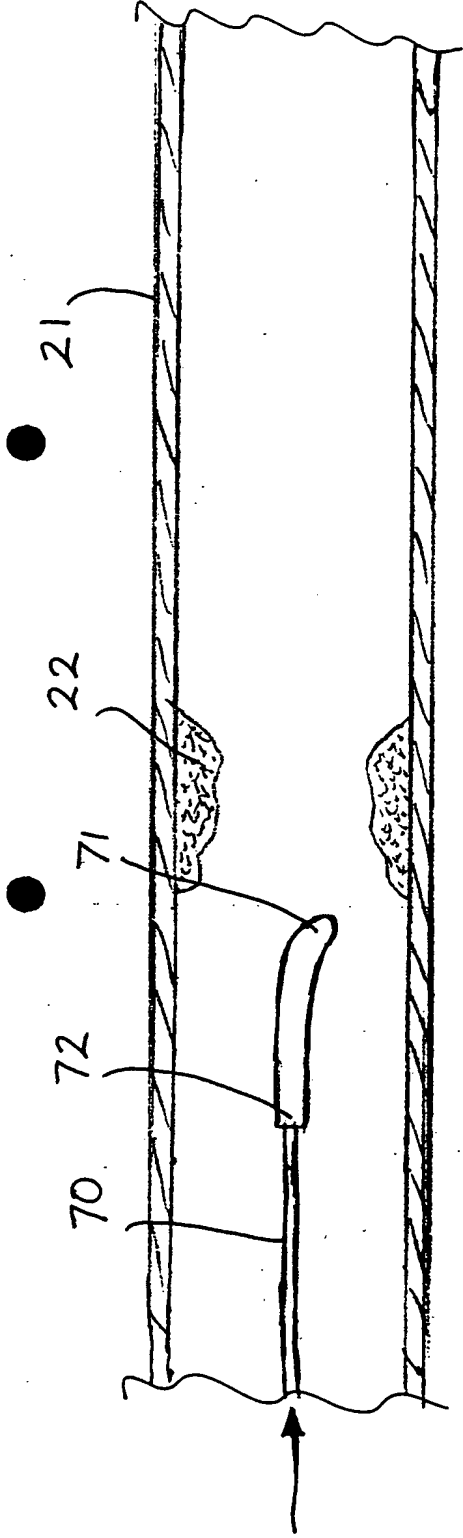


Fig. 14

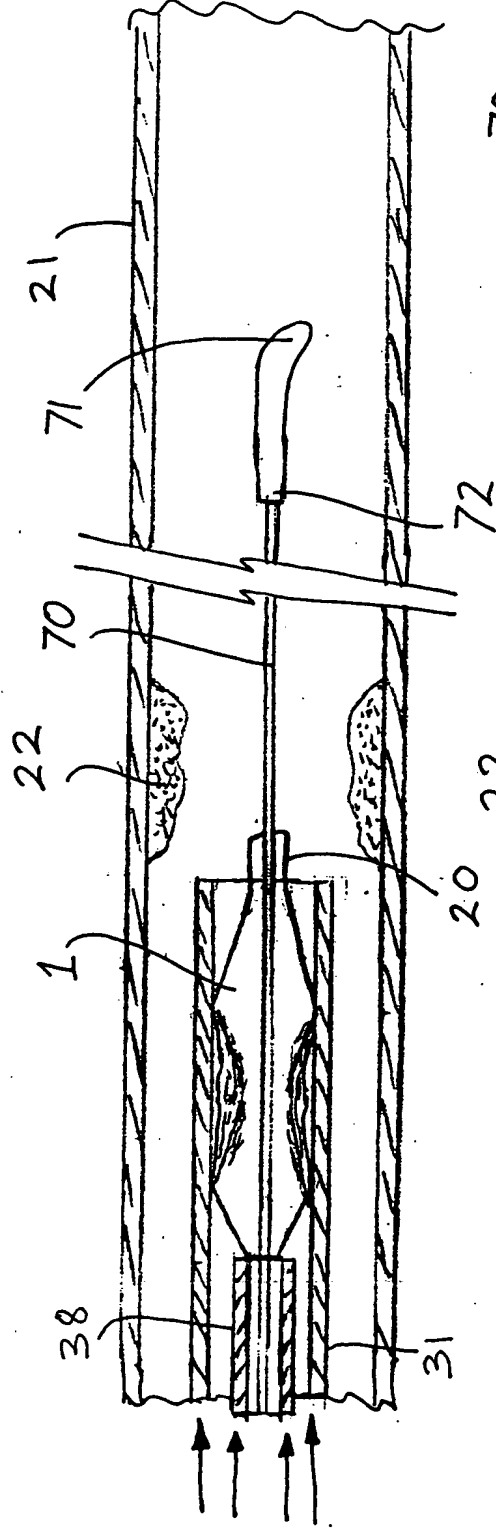
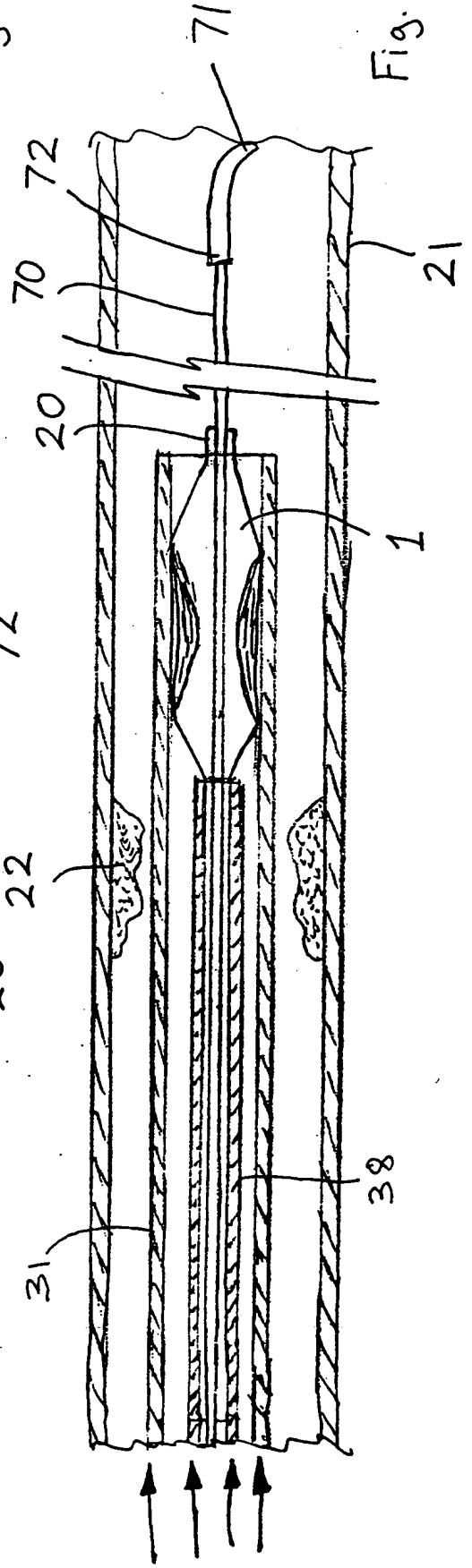
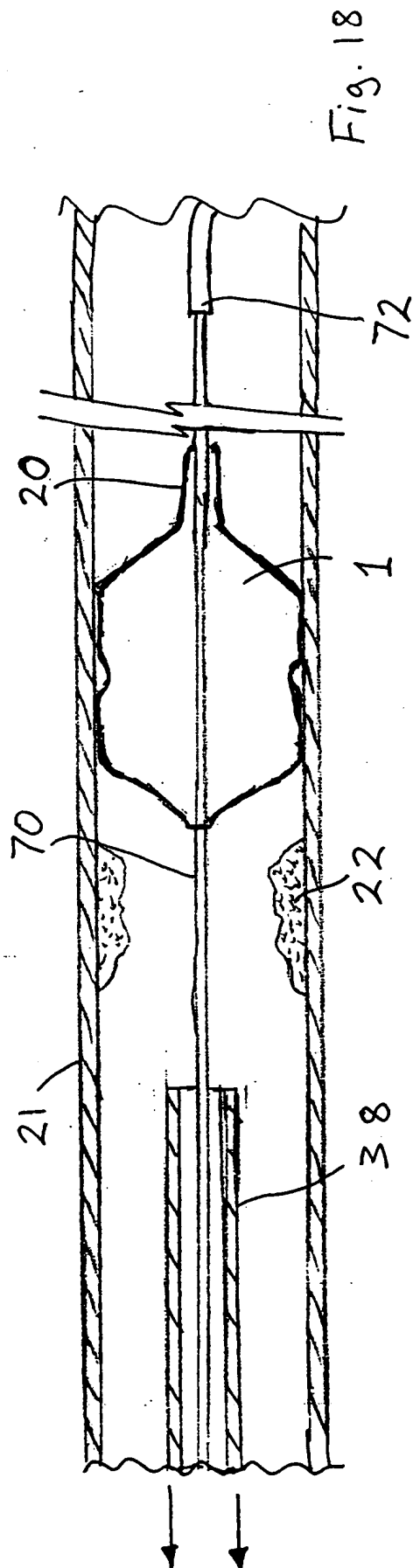
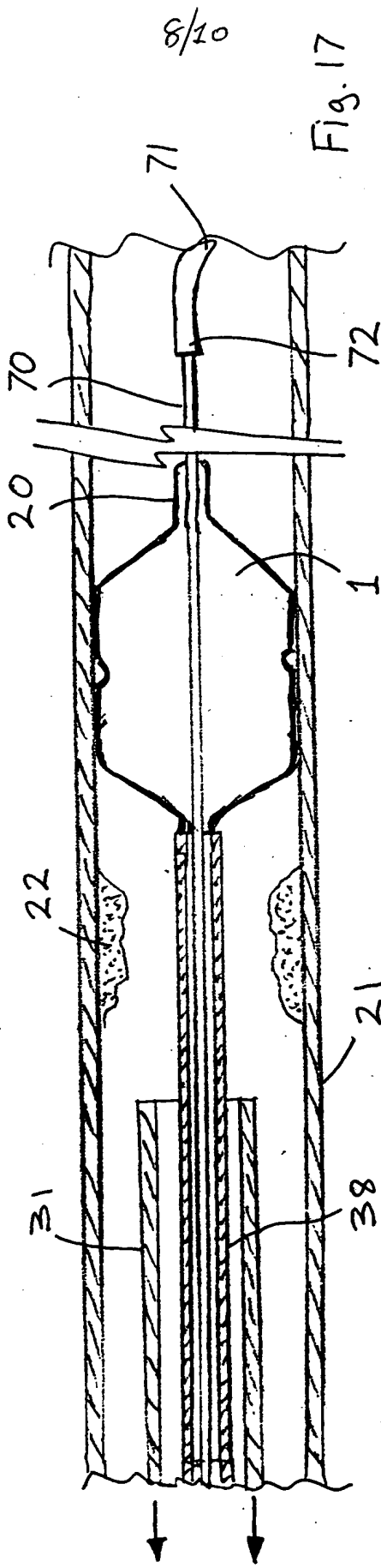
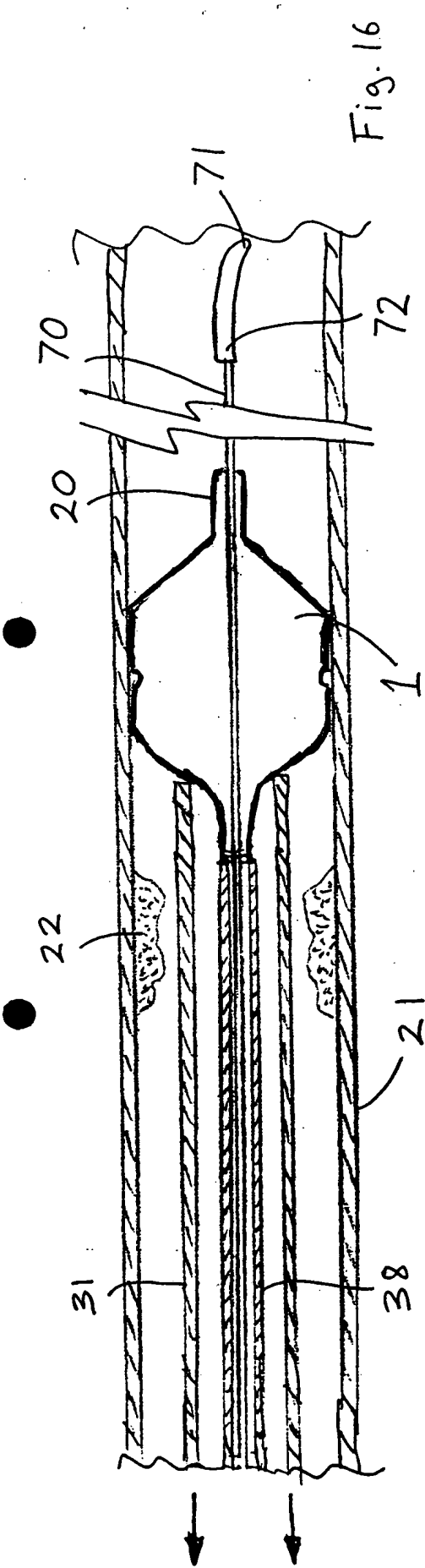


Fig. 15





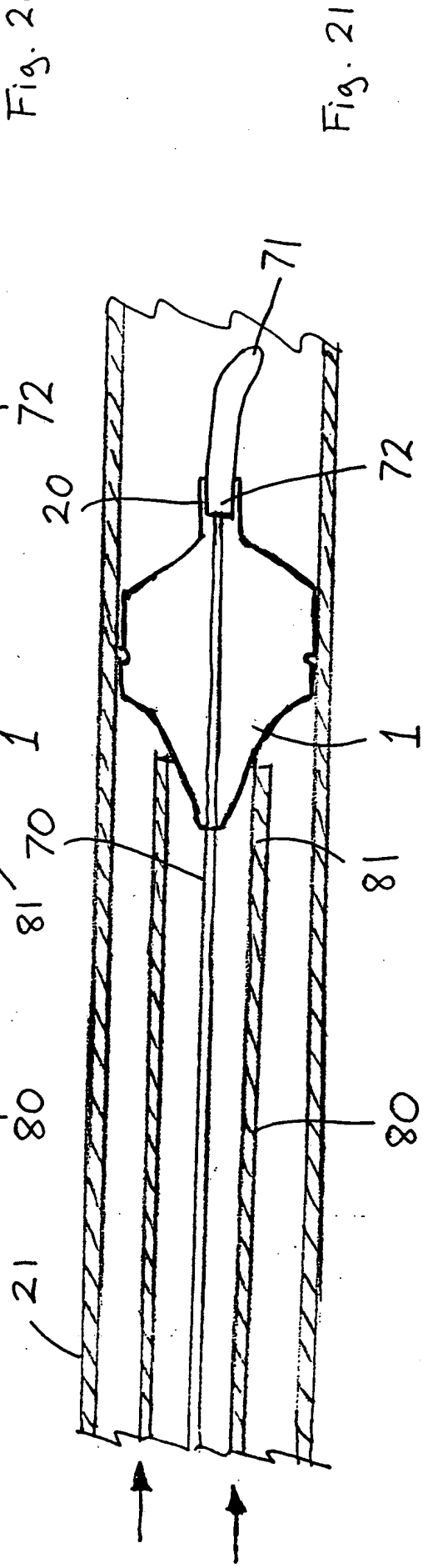
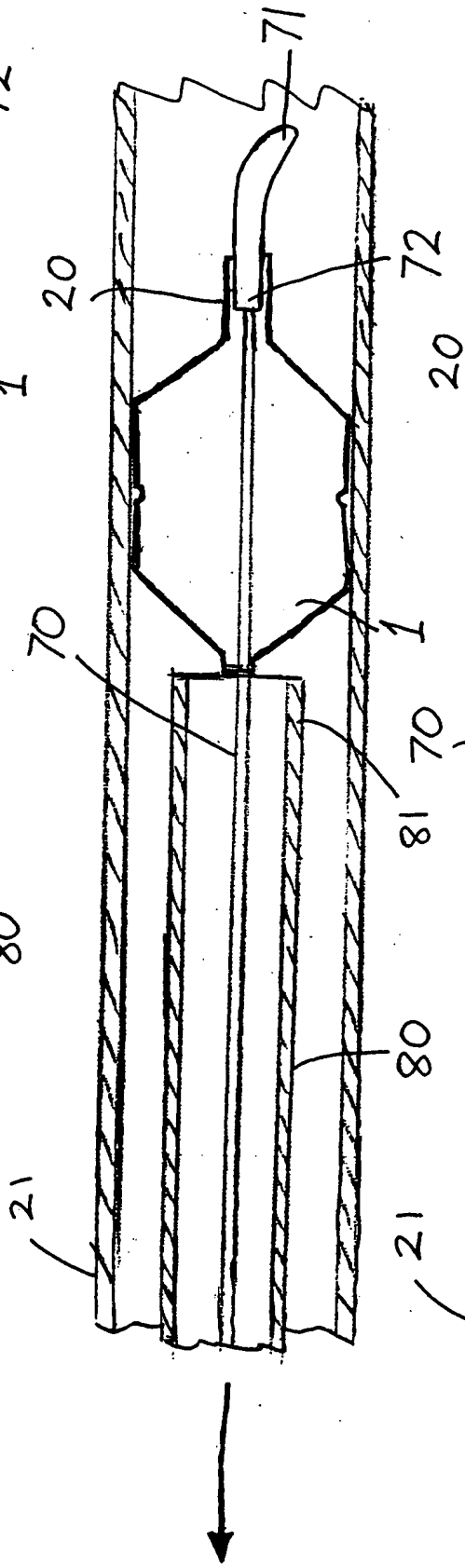
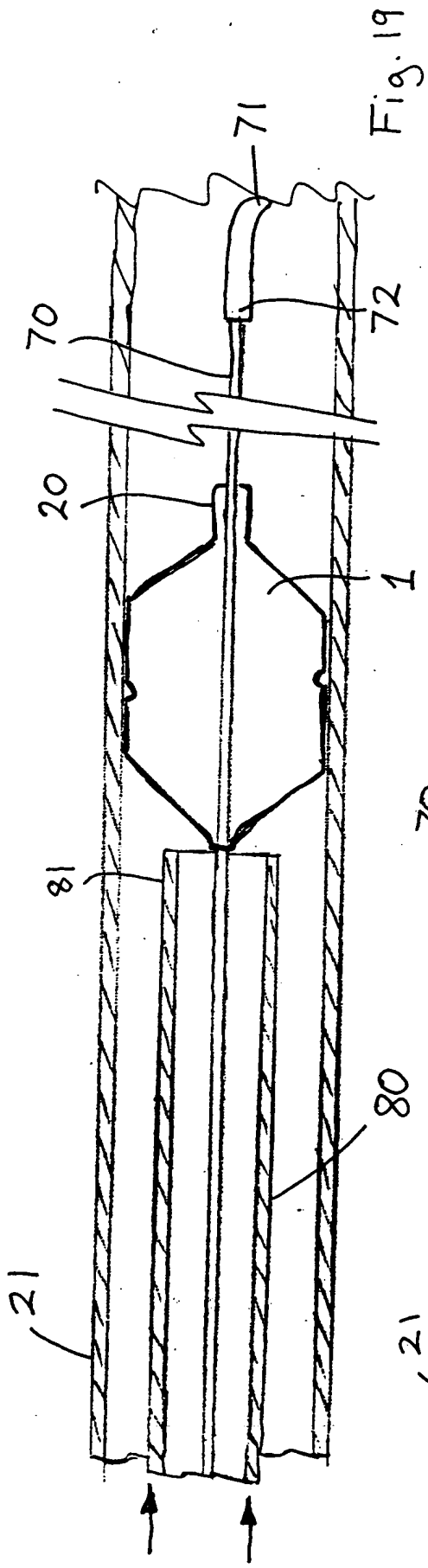


Fig. 22

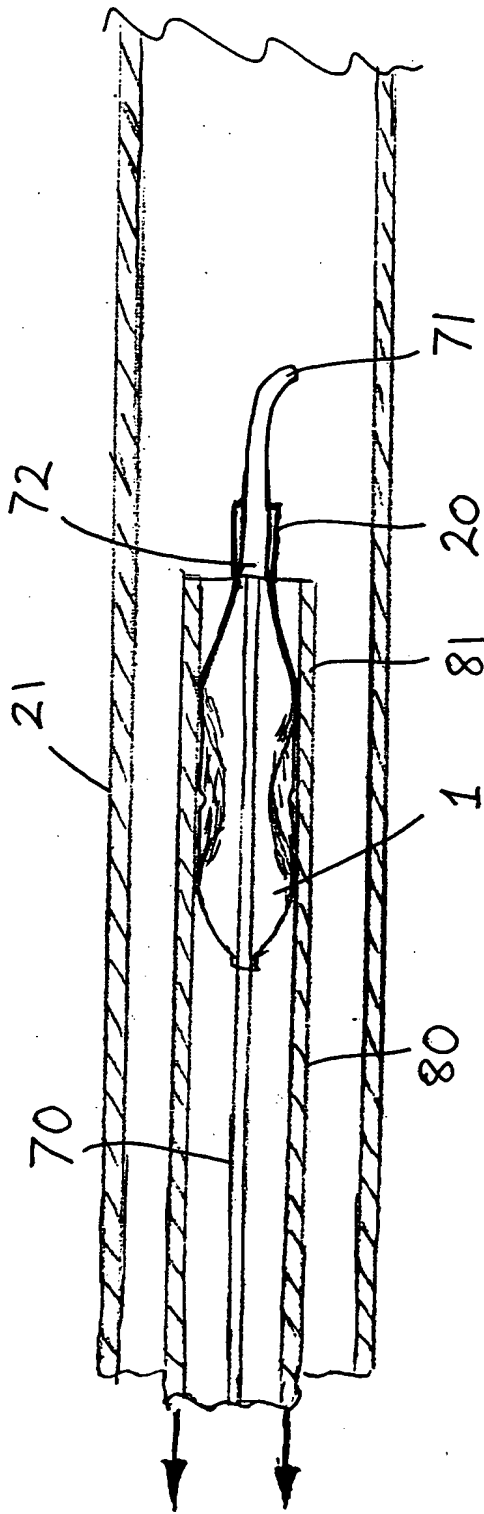


Fig. 23

